Complete Summary

GUIDELINE TITLE

HIV prophylaxis following occupational exposure.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. HIV prophylaxis following occupational exposure. New York (NY): New York State Department of Health; 2004 Jun. 41 p. [17 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. HIV prophylaxis following occupational exposure. New York (NY): New York State Department of Health; 2003 Sep. 39 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Hepatitis B virus (HBV) infection
- Hepatitis C virus (HCV) infection

GUIDELINE CATEGORY

Counseling
Evaluation

Management
Prevention

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Clinical Laboratory Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To develop guidelines for effective management of human immunodeficiency virus (HIV) prophylaxis in health care workers

TARGET POPULATION

Health care workers after occupational exposure to human immunodeficiency virus (HIV) or hepatitis B virus or hepatitis C virus

INTERVENTIONS AND PRACTICES CONSIDERED

Management of Occupational Exposure to Human Immunodeficiency Virus (HIV)

1. Recording information about the occupational exposure to HIV in the health care worker's confidential medical record
2. Cleansing of wound and skin sites exposed to HIV
3. Voluntary HIV testing after specific informed consent
4. Use of OraQuick rapid blood test for HIV testing, followed by Western blot assay for confirmation
5. Initiation of post-exposure prophylaxis (PEP) with highly active antiretroviral therapy (HAART), including zidovudine (ZDV, AZT, Retrovir) + lamivudine (3TC, Epivir) (or Combivir) plus tenofovir (Viread)
6. Initiation of alternative PEP agents (nelfinavir [Viracept], stavudine [d4T, Zerit], nevirapine [Viramune]*, efavirenz [Sustiva], indinavir [Crixivan], lopinavir/ritonavir [Kaletra] in the setting of drug intolerance or toxicity to recommended agents
7. Baseline confidential HIV testing within 72 hours of initiating HAART
8. Referral to experienced clinician within 72 hours of initiating HAART

9. Close monitoring of individuals receiving PEP, including complete blood count with differential, serum liver enzymes, HIV antibody tests, and signs of drug toxicity
10. Special considerations for pregnant healthcare workers exposed to HIV, including counseling on risks and benefits of HAART to the woman and her fetus

*Note from the National Guideline Clearinghouse: On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm3 unless benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the FDA Web site for more information (http://www.fda.gov/cder/drug/advisory/Nevirapine.htm).

Management of Occupational Exposure to Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)

1. Initiation of hepatitis B vaccine series to workers with potential exposure to blood and body fluids
2. Administration of hepatitis B immune globulin and initiation of hepatitis B vaccine series if worker is exposed to a source patient with acute or chronic hepatitis B
3. Determination of source patient's HBV and HCV serologic status
4. Baseline HCV serology and serum alanine aminotransferase, with repeated assessments at 4 and 6 months
5. HCV antibody and qualitative HCV viral load (HCV ribonucleic acid polymerase chain reaction)
6. Referral to clinician with experience in treating HCV

MAJOR OUTCOMES CONSIDERED

- Rate of transmission of human immunodeficiency virus (HIV), or hepatitis B virus (BHV) or hepatitis C virus (HCV) from an occupational exposure
- Efficacy of post-exposure prophylaxis (PEP) in reducing risk of transmission
- Risk of toxicity or other adverse effects from medications used for PEP

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person 3 to 4 times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

Methodology Specific to These Guidelines

To develop these guidelines for occupational post-exposure prophylaxis (PEP), the New York State Department of Health/AIDS Institute (NYSDOH AI) has reviewed the available PEP studies, the current standards for the use of highly active

antiretroviral therapy (HAART) in established HIV infection, and other issues that would affect the timely administration of optimal PEP. These guidelines update the previously issued guidelines of 2001 and include new recommendations for the initial recommended regimen for PEP.

Because there are no clinical trials on which to definitively base recommendations, the New York State Department of Health AIDS Institute guidelines are based on best practice evidence and constitute the considered opinion of a group of expert clinicians in the field of adult HIV medicine.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline developers compared their recommendations to those published by the Centers for Disease Control and Prevention (CDC). Refer to Appendix B in the original guideline document, titled "Occupational Exposure to HIV: Comparison of NYSDOH and CDC Recommendations."

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

These guidelines update the previously issued guidelines of 2001 and include new recommendations for the initial recommended regimen for post-exposure prophylaxis (PEP).

Rationale for PEP

The Committee recommends the use of highly active antiretroviral therapy (HAART) regimens for all significant risk occupational exposures when the health care worker (HCW) is evaluated within 36 hours of exposure.

Recording Information Following Occupational Exposure

When an occupational exposure occurs, the following information should be recorded in the HCW's confidential medical record:

- Date and time of the exposure
- Details of the procedure being performed and the use of protective equipment at the time of the exposure
- The type, severity, and amount of fluid to which the HCW was exposed
- Details about the exposure source
- Medical documentation that provides details about post-exposure management

General Management Considerations

Wound and skin sites should be cleansed with soap and water immediately. Exposed mucous membranes should be flushed with water.

PEP is recommended for exposure to blood or visibly bloody fluid or other potentially infectious material (e.g., semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids) associated with potential human immunodeficiency virus (HIV) transmission and in any of the following exposure situations:

- Break in the skin by a sharp object (including both hollow-bore and cutting needles or broken glassware) that is contaminated with blood, visibly bloody fluid, or other potentially infectious material, or that has been in the source patient's blood vessel
- Bite from an HIV-infected patient with visible bleeding in the mouth that causes bleeding in the HCW
- Splash of blood, visibly bloody fluid, or other potentially infectious material to a mucosal surface (mouth, nose, or eyes)
- A non-intact skin (e.g., dermatitis, chapped skin, abrasion, or open wound) exposure to blood, visibly bloody fluid, or other potentially infectious material

If HIV serostatus of the source is unknown, voluntary HIV testing of the source should be sought. In New York State, specific informed consent for HIV testing is required.

If the OraQuick rapid blood test is available on site, it should be used to determine the HIV status of the source patient. Results are usually available within 30 minutes of testing. Rules regarding confidentiality and consent for this test are identical to those for other HIV tests.

If the preliminary OraQuick rapid test result is positive, the result should be given to the source patient. To establish a diagnosis of HIV infection, the test must be confirmed by a Western blot assay, which should be performed as soon as possible.

If the result from testing the source patient is not immediately available and PEP is indicated based on assessment, the initiation of PEP should not be delayed pending the test result.

The New York State Department of Health/AIDS Institute (NYSDOH AI) Medical Care Criteria Committee believes that the critical decision point should be to determine whether the HCW has had a percutaneous, mucocutaneous, or non-

intact skin exposure to potentially HIV-infected blood, visibly bloody fluid, or other potentially infectious material. For these exposures, prompt initiation of PEP followed by telephone or in-person consultation with a clinician experienced in HIV PEP is recommended.

Implementing PEP

PEP should be initiated as soon as possible, ideally within 2 hours and no later than 36 hours post-exposure. The prescribing provider should ensure that the patient has access to the full course of antiretroviral (ARV) medications.

HAART is always recommended as the regimen of choice for at-risk exposures. Any variance from the recommended regimens should be made in consultation with an HIV Specialist or an occupational health clinician experienced in providing PEP (see HIV Specialist Policy in the "Companion Documents" field).

ARV medications for PEP should be readily available to HCWs who sustain a known or highly suspect occupational exposure to HIV. In establishing plans for providing PEP, employers should determine the following:

- How PEP will be made available within 1 to 2 hours of an exposure
- How a 24- to 48-hour supply of PEP will be made available for urgent use
- Who will be given authority for releasing drugs for this purpose
- How the HCW will obtain PEP drugs to complete the 4-week regimen (some individuals may be reluctant to go to their local pharmacy)

Confidential baseline HIV antibody testing of the HCW should be obtained at the time the occupational exposure is reported or within 72 hours of initiating PEP.

Confidential HIV testing of the source should be obtained as soon as possible after the exposure. A special consent form for testing the source patient is available and must be used (see Appendix C in the original guideline document).

If the source patient's HIV test result is negative, the HCW should be informed of the small chance that it could be a false-negative result if the source patient has been recently infected. PEP should be recommended in situations when a significant risk exposure has occurred and the clinician suspects that the source patient has a strong likelihood of having recently acquired HIV infection.

If a recommendation to begin PEP is declined, this decision should be documented in the medical record of the HCW.

All patients placed on PEP should be re-evaluated within 72 hours of their exposure. This allows for further clarification of the nature of the exposure, review of available source patient serologies, and evaluation of adherence to and toxicities associated with the PEP regimen.

A total of 4 weeks of treatment is recommended. This treatment duration is based on animal data and is generally recommended by HIV Specialists.

If an HCW presents for evaluation of a high-risk exposure at a time >36 hours after the incident, close monitoring of the HCW for signs and symptoms of acute HIV infection is recommended with subsequent introduction of HAART if acute seroconversion occurs (see Figure 1, which provides a clinical algorithm for "PEP Following Occupational Exposure," in the original guideline document).

Recommended PEP Regimens

The preferred PEP regimen is zidovudine 300 mg orally twice a day (po bid) + lamivudine 150 mg po bid (or co-formulated as Combivir 1 bid) plus tenofovir 300 mg orally once per day (po qd). Alternative agents may be used in the setting of drug intolerance or toxicity (see Table 3 and Appendix A in the original guideline document).

The PEP regimen should be continued for 4 weeks.

When the patient is known to be HIV infected and information regarding previous ARV therapy, current level of viral suppression, or genotypic/phenotypic resistance profile is available, the clinician, in consultation with an HIV Specialist, should individualize the regimen to more effectively suppress viral replication.

Monitoring the HCW Following Occupational Exposure

Clinicians should closely monitor people receiving PEP to detect ARV-induced toxicities (See the National Guideline Clearinghouse [NGC] summary of the New York State Department of Health guideline Antiretroviral Therapy for monitoring recommendations).

Because of the complexity and potential adverse effects of the treatment regimens, longitudinal care of the exposed HCW should be provided either directly by or in consultation with an HIV Specialist or an experienced occupational health clinician who is familiar with the most current PEP guidelines.

Sequential confidential HIV testing should be obtained at baseline, 1, 3, and 6 months post-exposure even if PEP is declined (see Table 4, "Monitoring Recommendations after Initiation of PEP Regimen Following Occupational Exposure Among HCWs" in the original guideline document). In New York State, if the test result is positive, a Western blot assay must be performed to confirm the diagnosis of HIV infection. See Appendices D and E of the original guideline document for specific counseling recommendations.

Any acute febrile illness following HIV exposure accompanied by one or more of the following signs or symptoms--rash, lymphadenopathy, myalgias, sore throat--suggests the possibility of acute HIV seroconversion and requires urgent evaluation. If this constellation of complaints is encountered, consultation with an HIV Specialist should be sought for optimal diagnostic testing and treatment options.

The HCW should be evaluated weekly over the first month to assess PEP adherence, adverse effects of the ARV therapy, interval physical complaints, and emotional status. (See the National Guideline Clearinghouse [NGC] summary of

the New York State Department of Health guideline Antiretroviral Therapy for monitoring recommendations, adverse drug effects, and important drug interactions).

PEP for the Pregnant HCW

Before administering PEP to a pregnant woman, the clinician should discuss the potential benefits and risks to her and to the fetus. Drugs to avoid during pregnancy include the following:

- Efavirenz
- Amprenavir in the second or third trimester
- Combination of stavudine and didanosine

Based on increasing clinical experience with HAART, PEP is indicated at any time during pregnancy when a significant exposure has occurred, despite possible risk to the woman and the fetus. Expert consultation should be sought. A decision about the initiation of PEP should be made within 36 hours of exposure, which is the period for optimal prophylaxis.

Efavirenz, which has been associated with teratogenicity in monkeys, should not be used in pregnant women.

Amprenavir should be avoided in the second and third trimesters because it may induce fetal skeletal ossification.

The combination of didanosine and stavudine should be avoided due to an increased risk of mitochondrial toxicity in pregnant women.

For women who may have been exposed to HIV through occupational exposure, breastfeeding should be avoided for 6 months after the exposure. Because HIV infection is most often diagnosed within 3 months of exposure, women who would prefer to breastfeed between 3 to 6 months following exposure should carefully discuss the risks and benefits with their clinicians.

Occupational PEP For Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)

The hepatitis B vaccine series should be initiated in non-HBV-immune HCWs who sustain a blood or body fluid exposure.

Administration of prophylactic hepatitis B immune globulin (HBIG) and the initiation of the hepatitis B vaccine series are recommended when the non-HBV-immune HCW is exposed to a source patient with acute or chronic HBV (see Table 6 titled "Recommended Post-Exposure Prophylaxis for Occupational Exposure to Hepatitis B Virus," in the original guideline document).

Following an occupational exposure, the source patient's HBV and hepatitis C (HCV) serologic status should be determined.

If the source patient is known to be HCV-antibody positive or if the serostatus is unknown, baseline HCV serology and serum alanine aminotransferase (ALT)

should be obtained from the exposed HCW and should be repeated at 4 to 6 months post-exposure.

If the source patient is known to be HCV-antibody positive, an HCV antibody and qualitative HCV viral load (HCV ribonucleic acid polymerase chain reaction [RNA PCR]) should be obtained from the exposed HCW 4 weeks after exposure.

In the setting of an acute elevation of ALT in the exposed HCW in the first 24 weeks post-exposure, a qualitative HCV RNA PCR should be obtained.

When HCV infection is identified early, the HCW should be referred for medical management to a clinician with experience in treating HCV.

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for "Post-Exposure Prophylaxis (PEP) Following Occupational Exposure."

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation. Because there are no clinical trials on which to definitively base recommendations, the New York State Department of Health AIDS Institute (NYSDOH AI) guidelines are based on best practice evidence and constitute the considered opinion of a group of expert clinicians in the field of adult human immunodeficiency virus (HIV) medicine.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Effective management of post-exposure prophylaxis (PEP) for human immunodeficiency virus (HIV) and hepatitis B and C virus in health care workers
- Reduction in risk of transmission of HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) after occupational exposure

POTENTIAL HARMS

- Medications used for post-exposure prophylaxis have risks of toxicity. Please refer to Appendix A of the original guideline document for information on toxicity, dose adjustments, and use in pregnancy for specific antiretroviral drugs.
- Although birth defects and adverse effects on human fetuses have generally not been associated with the currently available antiretroviral (ARV) agents, exposure of a fetus to ARV agents during pregnancy carries a theoretical risk of teratogenicity.

- Human immunodeficiency virus (HIV) testing can result in a false-negative test.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Tenofovir is contraindicated when creatinine clearance is <60 mL/min.
- The reverse transcriptase inhibitors may be contraindicated or may require dose reduction in the setting of renal insufficiency.
- Efavirenz administered to pregnant monkeys has been associated with birth defects and is therefore contraindicated in pregnancy.
- Amprenavir should be avoided in the second and third trimesters because it may induce fetal skeletal ossification.
- The combination of didanosine and stavudine should be avoided due to an increased risk of mitochondrial toxicity in pregnant women.

QUALIFYING STATEMENTS

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The New York State Department of Health AIDS Institute (NYSDOH AI) recommendations differ from those published by the Centers for Disease Control and Prevention (CDC) (see Appendix B in the original guideline document). The consensus opinion of the guideline committee continues to support a more aggressive approach to block human immunodeficiency virus (HIV) infection after occupational exposure. The recommendation to initiate post-exposure prophylaxis (PEP) must take into account the potential benefit of preventing infection versus the risk of toxicity from the medications used for PEP.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (HIV clinical practice guidelines, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience.
- Define target audience (providers, consumers, support service providers).
    - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)?
- Define implementation methods.
    - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes.
    - What steps need to be taken to make these activities happen?
    - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?
    - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
    - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress.
    - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate.
    - Did the processes and strategies work? Were the guidelines implemented?
    - What could be improved in future endeavors?

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. HIV prophylaxis following occupational exposure. New York (NY): New York State Department of Health; 2004 Jun. 41 p. [17 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Mar (revised 2004 Jun)

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. HIV prophylaxis following occupational exposure. New York (NY): New York State Department of Health; 2003 Sep. 39 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- HIV prophylaxis following occupational exposure. Tables and recommendations. New York (NY): New York State Department of Health; 2003 Jun. 35 p. Electronic copies: Available in Portable Document Format (PDF) from the New York State Department of Health AIDS Institute Web site.
- Post-exposure prophylaxis quick reference card. New York (NY): New York State Department of Health; 2003, Sept. Electronic copies: Available in Portable Document Format (PDF) from the New York State Department of Health AIDS Institute Web site.
- HIV specialist policy. New York (NY): New York State Department of Health; 2003 Mar. Electronic copies: Available in Portable Document Format (PDF) from the New York State Department of Health AIDS Institute Web site.
- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

Additionally, an Informed Consent Form (DOH-4054) is available in Appendix C of the original guideline document. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 18, 2004. This NGC summary was updated by ECRI on January 11, 2005.

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